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Lone Andersen

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EXAMINER

DEES, NIKKI H

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/529,137
Filing Date: September 06, 2005
Appellant(s): ANDERSEN ET AL.

Richard J. Basile
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 2, 2009, appealing from the Office action mailed December 17, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: It is noted that the obvious double patenting rejections are not presented for appeal.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

| | | |
|------------------------------------|----------------|---------|
| 5672367 | Grijpma et al. | 9-1997 |
| 5433960 | Meyers | 7-1995 |
| 6153231 | Li et al. | 11-2000 |
| WO 01/47368 Goldberg et al. 7-2001 | | |

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-39 and 49-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grijpma et al. (5,672,367, cols. 1-3).

Grijpma et al. discloses a chewing gum, free of non-biodegradable polymers (claim 32), and including one or more biodegradable polymers as claimed by applicant, in the amounts claimed by applicant and obtained using the procedure claimed by applicant (claims 6-10, 33-36, 50-55). The chewing gum also includes conventional chewing gum ingredients, including a medicinal active agent (claim 31), as claimed by applicant in the amounts claimed by applicant (claims 1, 12, 14, 15, 18-31, 37-39, 49, 55). Finding the optimum amount of water and flavoring agents to be included in the chewing gum (claims 1-6, 16, 17) would require nothing more than routine experimentation by one reasonably skilled in this art. Grijpma et al. teaches that the biodegradable polymers of their invention are known to be hydrolytically unstable (col. 1 lines 39-41). Additionally, one of ordinary skill would have recognized that the absence of water provides for an unpleasantly dry chewing gum product. Therefore, one of ordinary skill wishing to employ the biodegradable polymers of the prior art would have found it obvious to have formulated a chewing gum comprising the minimal amount of water to maintain the stability of the polymers while at the same time providing sufficient moisture to provide a chewing gum having pleasing textural properties.

The use of erythritol (claim 13) is a well known and viable alternative for other sugar alcohol sweeteners disclosed in the primary reference.

Claims 40-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grijpma et al. as applied to the claims above, and further in view of Meyers (5,433,960, cols. 3 & 9-13 and claims 1, 16, 27).

It would have been obvious to coat the chewing gum in Grijpma et al. with a coating as claimed by applicant in order to provide storage stability to the chewing gum since it is well known to coat chewing gum products with each of applicant's claimed coating materials in order to achieve this objective, as evidenced by Meyers.

Claims 1-30, 32-42, 46, 47 and 49-55 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al. (WO 01/47368, pages 4-7, 9-15, 17, 19, 42).

Goldberg et al discloses a chewing gum, free of non-biodegradable polymers (claim 32), and including one or more biodegradable polymers as claimed by applicant, in the amounts claimed by applicant and obtained using the procedure claimed by applicant (claims 6-10, 33-36, 50-55). The chewing gum also includes conventional chewing gum ingredients as claimed by applicant in the amounts claimed by applicant (claims 1, 12, 14, 15, 18-30, 37-39, 49, 55). Further, the chewing gum in Goldberg et al can be coated with a coating syrup (page 9 of Goldberg et al and applicant's claims 40-42, 46, 47). Finding the optimum amount of water and flavoring agents to be included in the chewing gum (claims 1-6, 16, 17) would require nothing more than routine experimentation by one reasonably skilled in this art. It was known in the art at the time the invention was made that biodegradable polymers were hydrolytically unstable.

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Additionally, one of ordinary skill would have recognized that the absence of water provides for an unpleasantly dry chewing gum product. Therefore, one of ordinary skill wishing to employ the biodegradable polymers of the prior art would have found it obvious to have formulated a chewing gum comprising the minimal amount of water to maintain the stability of the polymers while at the same time providing sufficient moisture to provide a chewing gum having pleasing textural properties.

The use of erythritol (claim 13) is a well known and viable alternative for other sugar alcohol sweeteners disclosed in the primary reference.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al. as applied to the claims above, and further in view of Grijpma et al. (col. 3, line 4) or Li et al. (6,153,231, col. 7, lines 60-61).

It would have been obvious to include a medicinal or pharmaceutical ingredient as an active ingredient in the chewing gum of Goldberg et al since such an ingredient is a conventional chewing gum component, as evidenced by either secondary reference.

Claims 43-45 and 48 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al. as applied to the claims above, and further in view of Meyers.

It would have been obvious to coat the chewing gum in Grijpma et al. with a coating as claimed by applicant in order to provide storage stability to the chewing gum

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since it is well known to coat chewing gum products with each of applicant's claimed coating materials in order to achieve this objective, as evidenced by Meyers.

Claims 1-55 are further provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims: 1-62 of copending Application No. 10/472,122; claims 1-54 of copending Application No. 10/472,154; claims 1-67 of copending Application No. 10/528,926; claims 1-64 of copending Application No. 10/528,930; claims 1-57 of copending Application No. 10/528,927; claims 1-1-20, 22-26 and 28-42 of copending Application No. 10/529,133 and claims 1, 2, 10, 11, 13-18, 24-26 and 28-54 of copending Application No. 11/088,109.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the chewing gum claimed in the claims of each of said applications is merely an obvious variation of the chewing gum claimed by applicant in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

(10) Response to Argument

It is noted that the Section G. of Appellant's arguments is directed to the obviousness type double patenting rejections. These rejections are not argued. The

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Board is requested to summarily affirm the obviousness type double patenting rejections.

Regarding the 103(a) rejection of claims 1-39 and 49-55 over Grijpma et al. (5,672,367).

Appellant claims a chewing gum having a low moisture content, i.e. a moisture content between 0.01 to 2.0 weight percent water by weight of the chewing gum.

Appellant argues that as Grijpma et al. do not address the moisture content of their chewing gum, and as the ingredients taught for use by Grijpma et al. in their chewing inherently contain water, the water content of the chewing gum of Grijpma et al. would have a water content higher than required by the pending claims.

Appellant goes on to retract a statement made in an earlier response regarding the knowledge of one skilled in the art regarding the degradation of biodegradable polymers in the presence of water.

Appellant's claim that a skilled artisan at the time of their invention would not have been aware that biodegradable polymers were hydrolytically unstable is contradicted by a statement in Grijpma et al. where, in regard to biodegradable polymers to be used in chewing gum compositions, it is noted that

Such chemically unstable bonds are preferably broken down under the influence of light or hydrolytically into components that are preferably water-soluble and non-toxic (col. 1 lines 39-41)

One of ordinary skill reading this statement would have clearly understood that it was, indeed, known at the time of Appellant's invention that the biodegradable polymers as

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taught by Grijpma et al. to be included in chewing gums were hydrolytically unstable, i.e. they break down in the presence of water. One of ordinary skill wishing to provide a chewing gum comprising biodegradable polymers with acceptable shelf-stability would have understood that the presence of excess water in combination with the biodegradable polymers would have been undesirable. The artisan would have endeavored to provide a chewing gum product comprising the minimal amount of water to provide a suitable texture to the chewing gum while at the same time providing a product with acceptable stability.

Similarly, Appellant's arguments that one of ordinary skill following the teachings of Grijpma et al. would not consider the water content of the chewing gum critical (p.20) are not convincing for the reason that the hydrolytic instability of the polymers was known. Therefore, the exposure of the polymers to excess water would have been of concern to the artisan.

Appellant goes on to argue that the amount of softeners taught for use in the invention of Grijpma et al. would lead to a water content higher than that of the pending claims. Grijpma et al. teach 0.5 to 15 % by weight of their chewing gum composition as softeners. Appellants' claim 29 is to their invention comprising softeners ranging from 0 to 18 % by weight of the chewing gum composition. Softeners taught by Grijpma et al. include lecithin, a softener also claimed by Appellant in claim 28. As Grijpma et al. teach softeners including the same compounds in the same amounts as claimed by Appellant, it would be expected that the water content contributed by the softener of the

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prior art would not be significantly different from the water content provided by the softeners of the pending claims.

Regarding the 103(a) rejection of claims 40-48 over Grijpma et al.

(5,672,367) in view of Meyers (5,433,960).

Appellant argues that the teachings of Grijpma et al. in view of Meyers fails to teach, suggest, or motivate one skilled in the art to coat the chewing gum of Grijpma et al. to provide storage stability to a chewing gum as claimed by Appellant. It is argued that there is no guidance from Meyers as to the amount of water to be contained in a chewing gum product comprising biodegradable polymers.

Meyers pertains to the coating of chewing gums. There is no argument that the coating of chewing gum products is not well-known. Meyers further teaches that the coating material for chewing gum provides “increased moisture stability at ambient conditions” (Abstract). As set forth in the response to the arguments regarding the rejection of claims 1-39 and 49-55 over Grijpma et al., the disclosure of Grijpma et al. does provide motivation for one of ordinary skill to produce a chewing gum product comprising biodegradable polymers while having a low moisture content in order to minimize the degradation of said polymers. One of ordinary skill would have recognized that these chewing gum products could have been provided with additional moisture stability by providing the chewing gum product with a coating such as that taught by Meyers. As both the chewing gum comprising biodegradable polymers and the coating to provide additional moisture stability to a chewing gum product were known in the

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prior art at the time the invention was made, their combination to provide the predictable result of a coated chewing gum product is considered to be obvious. Appellant has provided no evidence of unexpected results in their chewing gum product as claimed.

Regarding the 103(a) rejection of claims 1-30, 32-42, 46, 47 and 49-55 over Goldberg et al. (WO 01/47368).

Appellant argues that Goldberg et al. does not provide any indication that the moisture content of the chewing gum product comprising biodegradable polymers should be limited as is required by the pending claims.

As is indicated by the general teachings of Grijpma et al., one of ordinary skill in the art at the time both the instant invention and the invention of Goldberg et al. were made would have recognized that biodegradable polymers were sensitive to the moisture content of the chewing gum product as the polymers were known to be hydrolytically unstable. The water uptake as taught by Goldberg et al. would be understood by one in the art to be the uptake of moisture as the gum was chewed, resulting in an increased perception of juiciness. This is not considered to be a teaching away from providing a chewing gum having a low moisture content. As Appellant states in their remarks, Goldberg et al. do not provide guidance as to the moisture content of their chewing gum product. However, as one of ordinary skill would have recognized that the polymers of Goldberg et al. were hydrolytically unstable, it would have been obvious to provide them in a chewing gum product having the minimal moisture content required to maintain a chewable texture.

Regarding the 103(a) rejection of claim 31 over Goldberg et al. as applied to claim 1 and further in view of Grijpma et al. (5,672,367) or Li et al. (6,153,231).

Appellant argues that there is no teaching, suggestion or motivation in the references to formulate a biodegradable chewing gum with low water content additionally comprising medicinally active substances.

As addressed in the response to the arguments directed towards Goldberg et al., the knowledge of one of ordinary skill in the art at the time the invention was made would have led to the production of a chewing gum product having a low moisture content due to the known hydrolytic instability of the biodegradable polymers comprising the chewing gum. As Goldberg et al. teaches a chewing gum product comprising biodegradable polymers, and both Li et al. and Grijmpa et al. teach chewing gum products comprising biodegradable polymers and active ingredients, one of ordinary skill wishing to add active ingredients to a chewing gum product comprising biodegradable polymers would have found it obvious to do so as the combination of active ingredients in chewing gum products was known in the prior art.

In response to appellant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning (p. 19), it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and

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does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

As laid out in the rejection and response to arguments, the hydrolytic instability of biodegradable polymers was recognized in the art at the time Appellant's invention was made. This knowledge, coupled with the knowledge that a too-dry chewing gum product is also not desirable, would have motivated one of ordinary skill to provide a chewing gum product having sufficient moisture to maintain a suitable texture in the chewing gum product while at the same time minimizing the degradation effects on the biodegradable polymer.

Appellant's arguments directed toward the absence of unexpected results and the failure of the primary references to disclose specific water content of their chewing gum product (p. 22) are addressed in the response to the arguments presented in support of the 103(a) rejections of claim 1 over Grijpma et al. and Goldberg et al. presented *supra*.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,

/Nikki H. Dees/

Examiner, Art Unit 1794

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